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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,369	08/29/2001	Ahmad Yekta	1191/IH584-US1	9064
7590	11/30/2004		EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			NILAND, PATRICK DENNIS	
		ART UNIT	PAPER NUMBER	
		1714		

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/943,369	YEKTA ET AL.
	Examiner	Art Unit
	Patrick D. Niland	1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17-31 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 17-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

1. The amendment of 9/8/04 has been entered. Claims 17-31 are pending.
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102

that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17-23 and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by US Pat. No. 6485703 Cote et al..

Cote discloses the instantly claimed composition at the abstract; column 6, lines 9-67; column 7, lines 45-47, which will necessarily give a viscosity change with pH change and/or with temperature change; column 8, lines 27-44; and the remainder of the document. The polymers will be amorphous and are therefore liquid by definition. Column 9, lines 55-65 falls within the scope of the instant claims 8-9. The mixture will necessarily be placed into an instrument's container, which falls within the scope of the instant claims 13-23 and 27. The applicant's argument re "consisting essentially of" is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude the properties argued by the applicant. "Consisting essentially of" does not exclude any other component of the patentee because no other component has been shown to materially affect the

basic and novel characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963) and *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the newly added claims necessarily occurs in the polymer of the patentee because it is a hydrogel.

The argument that the patentee does not disclose or suggest a process for preparing a standard, or a process for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. It is not seen that the recitation "for preparing a secondary standard" further defines the process by requiring anything other than the steps recited after "of:" nor that the method of the reference does not result in a product which could be used as a secondary standard. The applicant provides no evidence that an analyte sensitive material is not necessarily and inherently used as a standard because a standard need never contact said analyte by definition of "standard". Applicant's argument that the product of Cote contains the analyte is not persuasive since the analyte of the instant claims may be anything analyzable. The instant claims do not exclude the standard from containing or not containing the analyte nor do they specify what the analyte is. This argument does not distinguish over the reference therefore. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the

product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container. The applicant's arguments regarding the instant claim recitation of "dye in an amount effective to simulate a known amount of analyte" is not persuasive because any amount of any dye can be used to simulate some amount of some analyte under some analytical conditions. This limitation therefore encompasses any amount of dye that may be used by the patentee and therefore does not differentiate the instantly claimed inventions from those disclosed by the patentee. This rejection is therefore maintained.

5. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6485703 Cote et al. in view of US Pat. No. 6077669 Little et al..

Cote discloses the instantly claimed composition at the abstract; column 6, lines 9-67; column 7, lines 45-47, which will necessarily give a viscosity change with pH change and/or with temperature change; column 8, lines 27-44; and the remainder of the document. The polymers will be amorphous and are therefore liquid by definition. Column 9, lines 55-65 falls within the scope of the instant claims 8-9. The mixture will necessarily be placed into an instrument's container, which falls within the scope of the instant claims 13-23 and 27. The applicant's arguments regarding the instant claim recitation of "dye in an amount effective to simulate a known amount of analyte" is not persuasive because any amount of any dye can be used to simulate some amount of some analyte under some analytical conditions. This newly presented limitation therefore encompasses any amount of dye that may be used by the patentee and therefore does not differentiate the instantly claimed inventions from those disclosed by the patentee. It would have been obvious to one of ordinary skill in the art to use the HASE

polyurethanes of the instant claims because they are well known, commercially available hydrogel forming polymers and the patentee encompasses such polyethylene oxide based hydrogel forming polymers at column 6, lines 9-12 and 17-21. It would have been obvious to one of ordinary skill in the art to calibrate an instrument using these mixtures because the ordinary skilled artisan would recognize that the reading of the mixture without analyte must be determined to compare it with analyte containing material so that a meaningful value can be assigned to the analyte containing reading. This would be calibration or standardization and is discussed at column 8 of Little et al.. It would have been obvious to one of ordinary skill in the art to use ammonia gas to achieve whatever the desired pH should be because this is a well known manner to affect pH and would be readily applicable to the systems of Cote. The applicant's argument re "consisting essentially of" is not persuasive because the component that the applicant states that they wish to exclude of Cote is the component which falls within the scope of the instantly claimed viscosity changing polymers. The instant claims do not exclude the properties argued by the applicant. "Consisting essentially of" does not exclude any other component of the patentee because no other component has been shown to materially affect the basic and novel characteristics of the instant claims. The applicant has not shown the additional ingredients of the reference to materially affect the basic and novel characteristics of the composition. It is therefore not seen that "consisting essentially of" excludes anything from the composition of the reference. See *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963) and *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948). The "gelling" step of the newly added claims necessarily occurs in the polymer of the patentee because it is a hydrogel. The argument that the patentee does not disclose or suggest a process for preparing a standard, or

a process for preparing a container for calibrating an instrument, comprising gelling a mixture and therefore, Cote does not anticipate claims 17-23 and 27 is not persuasive because the patentee performs the instantly claimed method steps. The recited future intended use of the resulting product of the method of the patentee and the instant claims is not material in determining whether the process of the instant claims 17-23 and 27 is novel because it does not further limit the process of the instant claims so as to remove the process of the patentee as anticipating it because the product resulting from the process of the patentee necessarily and inherently can be used in these future processes and the product of the process of the patentee will be in some type of container. The applicant's arguments regarding whether or not Little discloses viscosity changing polymers is not persuasive because all polymers have the ability to change viscosity with some changing environmental factor such as temperature, pH, etc.. This argument ignores the reason for which Little was clearly cited above and the fact that Cote is the primary reference cited for this factor with Little cited to explain, as stated above. For the reasons stated in this paragraph and in paragraph 4 above, this rejection is therefore maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick D. Niland whose telephone number is 571-272-1121. The examiner can normally be reached on Monday to Thursday from 10 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick D. Niland
Primary Examiner
Art Unit 1714